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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,782	03/29/2001	Sunil Kumar Verma	U 013365-9	5526
7590	11/29/2004		EXAMINER	
Ladas & Parry 26 West 61st Street New York, NY 10023			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/821,782	VERMA ET AL.
Examiner	Art Unit	
Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 13 November 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 116 is/are pending in the application.  
4a) Of the above claim(s) 6-16 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-5 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a))

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_ .

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's election with traverse of Group I (claims 1-5) is acknowledged. The traversal is on the ground(s) that examiner has not met the burden of providing an example of a materially different process with which the claimed product can be used. This argument is fully considered and is found not persuasive because of the following reasons: (i) the specific process steps are not required to show burden of using the claimed product in a materially different process, and the general examples given by the examiner is sufficient to show that the product can be used in a materially different process (ii) separate classification search is *prima facie* evidence of burden, (iii) the issues are not the same with respect to 35 U.S.C. 112 and 35 U.S.C. 101 statutes, Further, Claims in Group I are drawn to product (primers) and the method steps are not required by the claims in Group II which are drawn to a method for identification of an animal. These two groups are patentably distinct as far as the subject matter is concerned, because Group I invention is directed to product, and invention in Group II is directed to method, which can be used in a materially different processes as discussed in the previous office action. Hence the restriction requirement is still deemed proper and is made FINAL.

2. This application is filed on March 29, 2001.
3. Claims 1-5 are considered for examination. Claims 6-16 are withdrawn from consideration in view of restriction/election, as being non-elected claims. This is made FINAL.

***Objections to the Specification***

- 4a. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see at least page 14 of the instant specification). Applicant is required

to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4b. Claims 2-5 are objected because these claim limitations does not appear to further limit the claim 1.

***Claim objections Sequence Rules***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

Claim 1 and 5 in the instant disclosure comprise nucleic acid sequences with more than 10 nucleotides, which are not identified by SEQ ID NO.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite nucleotide sequences which are unclear and indefinite because it is not clear what these sequences mean to these claims. Amendment to refer the sequences as SEQ ID No. would obviate the rejection.

B. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite 'mcb 398' and 'mcb 869', which are unclear and

indefinite because it is not clear what these terms mean to these claims. Amendment to refer the sequences as SEQ ID No. would obviate the rejection.

C. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-5 are indefinite over the recitation of "capable of amplifying" because capability is a latent characteristic and the claims do not set forth the criteria to determine capability. The meets and bounds of the claims are unclear. That is, it is not clear whether the recited mcb 398 and mcb 869 have the potential to amplify a fragment of cytochrome b gene or do in fact amplify the said fragment. Amendment of the claim to read, for example, "which amplifies" would obviate this rejection.

D. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 is indefinite because the meets and bounds of the claim are unclear. That is, it is not clear whether both the recited universal primers are required to amplify a fragment of cytochrome b gene or a single primer is sufficient to amplify a fragment of cytochrome b gene. If applicants' intend to claim both the primers, amendment to replace 'universal primers' with 'universal primer pair' would obviate this rejection.

E. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 is indefinite because the meets and bounds of the claims are unclear. That is, it is not clear whether the claim 1 refers to just primers or primer pair sequences or any sequences encompassing the primers or primer pairs. Further it is unclear how the claims

2-5 further limit the claim 1. Amendment to clarify the indefiniteness would obviate the rejection.

F. Claim 2 recites the limitation "the fragment of mitochondrial". There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites cytochrome b gene and claim 2 which is dependent on claim 1 recites the fragment of mitochondrial cytochrome b gene of claim 1, which lacks support for the said limitation in claim 2.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Matthee et al. (Mol. Phylogenet. Evolution., Vol. 12 (1), pp. 31-46, 1999).

Note : Claims are given the broadest scope of interpretation in view of the "comprising" format (having) of the instant claims. The following rejection is based on a nucleic acid sequence comprising the primer sequences and the term 'primer' in the preamble is broadly interpreted as a nucleic acid sequence.

Matthee et al. teach a nucleic acid sequence of claim 1 and 5, of mitochondrial DNA cytochrome b gene (1140 bp) comprising the sequences of mcb 398, mcb 869 and the sequence of the fragment of 398-869 as claimed in the instant claims (see enclosed sequence alignment from GenEmbl. database).

Thus the disclosure of Matthee et al. meets the limitations in the instant claims.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Note: For the following rejection, the term 'universal primers' has been interpreted to encompass a nucleic acid with a limited length for use in amplification, for example, polymerase chain reaction.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthee et al. (Mol. Phylogent. Evolution., Vol. 12 (1), pp. 31-46, 1999) in view of Kocher et al. (Proc. Natl. Acad. Sci. USA., Vol. 86, pp 6196-6200, 1989).

Matthee et al. teach a nucleic acid sequence of claim 1 and 5, of mitochondrial DNA cytochrome b gene (1140 bp) comprising the sequences of mcb 398, mcb 869 and the sequence of the fragment of 398-869 as claimed in the instant claims (see enclosed sequence alignment from GenEmbl. database).

With regard to claim claims 2-4, Matthee et al. also teach said fragment discriminates various evolutionary lineages (species/ subspecies) (page 44, FIG. 5), the fragment flanks highly conserved sequences amongst a vast range of animal species (see page 35, col. 2, paragraph 1 under result and discussion section, page 38, col. 2, paragraph 2), polymorphic interspecifically, but monomorphic at intra species sources (see page 31, abstract, and page 43, col. 2, paragraph 1 under conclusions section, page 44, FIG. 5, indicates no significant heterogeneity between taxa (genus level) (intra species), but variation within the species).

However Matthee et al. did not teach universal primer pair to amplify a fragment of cytochrome b gene.

Kocher et al. teach a method of amplifying a DNA segment of cytochrome b gene by designing a pair of primers flanking highly conserved region of cytochrome b gene (see page 6196, col. 2, paragraph 1 under materials and methods section). Kocher also teach sequence comparisons to identify evolutionary (phylogenetic) sequence variation among different species of animals extending from intraspecific to intergeneric level (see page 6198, col. 2, paragraph 2, Fig. 2, page 6199, col. 2, paragraph 2 under discussion section, Fig. 3).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made, to use the mitochondrial cytochrome b gene sequence as taught by Matthee et al. with a step to generate primers and primer pairs to amplify a target nucleotide sequence designed based on known target sequence (cytochrome b gene) because Kocher et al. taught the development and use of oligonucleotide primers based on the known highly conserved region of cytochrome b gene for a rapid and specific detection of animal species and to evaluate the pattern of molecular evolution in a variety of animal species (see page 6196, col. 2,

paragraph 1, paragraph 1 under materials and methods section). Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, to generate primers and primer pairs for the detection of various animal species using known sequence of cytochrome b gene as taught by Matthee et al. with primers designed for the general PCR method taught by Kocher et al. for the purpose of rapid detection of various animal species and to evaluate phylogenetic variation among species. The ordinary artisan would have had a reasonable expectation of success that primers to amplify a fragment of cytochrome b gene could be used for detection because Kocher et al. teach the efficient and successful use of primers for PCR to various animal species using known highly conserved sequence of the cytochrome b gene. The ordinary artisan would have been motivated to generate a number of primers and primer pairs for detection of various animal species, such primers and primer pairs are considered functionally equivalent to the claimed primers and primer pairs in the absence of secondary considerations.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 . The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*SP*  
Suryaprabha Chunduru  
November 22, 2004

*Jehanne Sitton*  
**JEHANNE SITTON**  
**PRIMARY EXAMINER**

11/22/04